



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

July 26, 2000

Ms. Kaye B. McDonald
Pharmaceutical Associates
Incorporated
201 Delaware Street
Greenville, SC 29605

Dear Ms. McDonald:

Your petition requesting the Food and Drug Administration to make a determination that an abbreviated new drug application is suitable for elixir containing 10 mg hydrocodone bitartrate/650 mg acetaminophen per 30 mL was received by this office on 07/20/00. It was assigned docket number 00P-1243/CP 2 and it was filed on 07/17/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler
Dockets Management Branch

00P-1243

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